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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,574	06/24/2003	John J. O'Mahony	3659-67	8253
23117	7590	08/25/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/601,574

Applicant(s)

O'MAHONY ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 and 27 June 2005.  
 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-39, 41-43, 45-57, 59-72 and 74-85 is/are pending in the application.  
 4a) Of the above claim(s) 37-39, 41-43, 45-57, 61-72 and 74-81 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 59, 60 and 82-85 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) ☐ Notice of Informal Patent Application (PTO-152)  
 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 59-60 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: any structure that detects leaks. The preamble alludes to a "leak detector...comprising" but never recites any element that is capable of performing a leak detecting function.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,690,831 to Kenley et al. Although applicant fails to set forth any elements of his device that are capable of detecting leaks, applicant has recited claim limitations drawn to a device that is anticipated by the prior art. Kenley discloses an extracorporeal treatment system with draw and return lines connected to the patient, a reversible blood pump (see column 26) that may create a negative pressure in the return line if the pump is reversed (also anticipating applicant's claim that a portion of the device is "adapted to"

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operate with a pump, since if there is a pump in the Kenley device, the rest of the components are capable of interacting with the pump), a filter, and a controller that operates the pumps.

5. Claims 59-60 of this application has been copied by the applicant from U. S. Patent No. 6,572,576. This claim is not patentable to the applicant because it is anticipated by the Kenley reference cited above.

An interference cannot be initiated since a prerequisite for interference under 37 CFR 1.606 is that the claim be patentable to the applicant subject to a judgment in the interference.

***Claim Rejections - 35 USC § 102/103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 82-85 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 5,690,831 to Kenley et al. Kenley discloses that leakage detectors may be employed at various points on the extracorporeal fluid circuit to detect leaks from the tubing or hardware components (see column 34, lines 5-15). Kenley clearly contemplates the use of leak detectors on the fluid lines of his device. In the alternative, Kenley does not specifically disclose a leak

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detector on the same fluid line as the blood pump, but rearranging parts of an invention involves only routine skill in the art. See MPEP § 2144.04.

***Response to Amendment/Arguments***

8. Applicant's amendment filed 20 June 2005 has been entered and considered.

9. Applicant's arguments filed 20 June 2005 have been fully considered but they are not persuasive. Applicant argues that the Kenley device does not anticipate the claimed invention since Kenley does not disclose reversing the blood pump to create a negative pressure in the return line. However, a pump necessarily creates a negative pressure upstream of the pump, and a positive pressure downstream. Therefore, if the Kenley blood pump is reversed, it necessarily creates a negative pressure in the return line. Furthermore, applicant's limitation is held to be a recitation of the intended use of the device, since it recites the manner of operation of an apparatus. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

10. Applicant further argues that the currently pending claims should be allowed for the same reasons the USPTO allowed the identical claims in US 6,572,576. However, MPEP § 2307.2 indicates that the examiner should determine whether the presented claims are unpatentable on any ground(s), including 35 USC 102 and 35 USC 103. Since the examiner has found such grounds for rejection, it is made herein.

***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

**TATYANA ZALUKAEVA  
PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'T. Zalukaeva', written in a cursive style.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd

10 August 2005